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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,801

09/28/2006

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,801	Applicant(s) MORINAGA ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/08, 3/31/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-7, 11-14, and 16-21 are currently pending. Claims 11-14 and 16-21 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 1-7 are withdrawn from consideration.

Election/Restrictions

Applicants' election of Group II (claims 11-14 and 16-21) in the reply filed on Nov. 25, 2008 is acknowledged. Applicant has elected Group II without traverse. Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided in English.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 11-14 and 16-21 are indefinite in the recitation "...wherein the first membrane has at least two layers having a biodegradable base layer and an adhesion preventive layer" in claim 11. It is not clear whether this limitation is intended to mean that *each* of the two layers of the first membrane has at least two layers (for a total of at least four layers), or whether the first membrane simply has two layers, one being the biodegradable base layer and the other being the adhesion preventive layer. This term is not defined by the claim, the specification does not provide a sufficient standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For the purposes of the rejections set forth below, the latter of these two interpretations has been applied.

B. Claim 12 recites the limitation "the tissue" in line two of the claim. There is insufficient antecedent basis for this limitation in the claim as two distinct types of tissue are recited in claim 11; injured or deficient tissue (i.e. the first type of tissue) and surrounding tissue (i.e. the second type of tissue). Thus it is not clear to which type of tissue the language in claim 12 is referring. MPEP 2173.05(e).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-14 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MATSUDA (U.S. 2003/0114061; Filed Dec. 12, 2002; Reference

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#1 under U.S. Patent Application Publications on IDS dated Feb. 25, 2008) in view of CALHOUN (U.S. 2004/0115241; Filed Sep. 9, 2002).

1. Matsuda discloses adhesion preventative membranes (abstract) comprised of a first membrane made of a collagen nonwoven fabric layer that provides membrane strength (corresponding to the instantly claimed biodegradable base layer). This biodegradable base layer may be laminated with a coating layer, containing a mixture of collagen and hyaluronic acid that prevents adhesion. Thus, the first membrane is at least two layers and has a biodegradable base layer and an adhesion preventative layer (paragraphs [0091], [0092] and [0163]; Examples 1 and 3; claims 1 and 2).

2. Matsuda teaches that the adhesion preventative membranes of the invention can be used for prosthesis and as a prosthetic membrane for deficient parts or cut surfaces of membranous tissues in the living body, such as pericardium (paragraphs [0001], [0192], and [0198]). Matsuda teaches that the materials are suitable for various kinds of prosthetic materials that can be used in known manners (paragraphs [0003], [0192], [0196], and [0197]). Matsuda does not explicitly teach sandwiching an injured tissue by two membranes or by a tissue-sandwiching part of one membrane.

3. However, one of ordinary skill in the art would know to apply the adhesion preventative membranes in this way. The skilled artisan would readily appreciate that it is important to prevent adhesion to all of the surrounding tissues adjacent to a damaged membrane (i.e. on both sides) as taught by Matsuda (paragraphs [0092], [0094], and [0095]). Furthermore, methods using adhesion preventative membranes to sandwich a particular site were well-known at the time of the invention.

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4. For example, Calhoun discloses anti-adhesion membranes for use with implants to prevent post-surgical adhesions between the implant and the surrounding tissue. Calhoun teaches a method of reducing adhesions resulting from a surgical implant comprising covering all the surfaces of the implant with a bioresorbable anti-adhesion membrane by sandwiching the implant within the membrane (paragraphs [0023] and [0028]; claims 1 and 5). Since the implant taught by Calhoun is the potential cause of the adhesions to be prevented, one of ordinary skill in the art would readily envisage sandwiching an injured or deficient tissue (which is also the cause of the adhesions to be prevented) by the similar adhesion preventing membranes of Matsuda.

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to sandwich an injured or deficient tissue between two membranes taught by Matsuda. One would have been motivated to do so since Matsuda does not disclose specific methods for the use of the disclosed membranes, but rather teaches that the inventive membranes can be used in known manners and in accordance with known methods (paragraphs [0192], [0196], and [0197]). While it is well within the skill of the ordinary artisan to determine the optimal placement of adhesion preventing membranes at the sites at which adhesion prevention is desired, the artisan would be motivated to look to the literature for guidance in the absence of specific teachings by Matsuda. Calhoun teaches a method of preventing adhesions using bioresorbable membranes to sandwich the cause of the adhesions. Therefore, an ordinary artisan would have had a high expectation of success by using the membranes of Matsuda to sandwich a damaged or deficient membrane (i.e. the

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cause of adhesions) as taught by Calhoun, to provide a suitable prosthetic membrane structure for healing of the damaged or deficient membrane. Claims 11-14 are obvious over Matsuda and Calhoun.

6. As stated above, Matsuda teaches adhesion preventive membranes having a base layer of collagen nonwoven fabric and having a coating layer (i.e. an adhesion preventive layer) containing a mixture of collagen and hyaluronic acid (paragraphs [0091], [0092] and [0163]; Examples 1 and 3; claims 1 and 2). Furthermore, Matsuda teaches that the coating layer containing the mixture of collagen and hyaluronic acid is sponge-like or film-like (i.e. a sheet) (paragraphs [0021], [0027], [0037], [0038], [0088]; Examples 1 and 3). Thus, the combination of Matsuda and Calhoun renders claims 16-21 obvious as well.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643